

REMARKS

Applicant thanks the Examiner for the courtesy extended in granting the interview with Applicant's representative on April 5, 2005.

Applicant respectfully requests reconsideration of the claims. Claims 1-9, 12 and 34 were previously pending in this application. By this amendment, Applicant is canceling claims 2-3, 5-11, 13-33 and 35-37 without prejudice or disclaimer. Claims 1, 12 and 34 have been amended. New claims 38-41 have been added. As a result, claims 1, 4, 12, 34 and 38-41 are pending for examination with claims 1, 40 and 41 being independent claims.

Claim 1 encompasses degenerate nucleic acids encoding the amino acid sequence of SEQ ID NO:30. This type of claim is explicitly approved in the USPTO written description guidelines (Example 11). Support for the amendment to claim 1 is found in claim 1 as filed and in the specification as filed, for example at page 12, lines 20-23.

Claim 12 has been amended to correct the dependency of the claim in view of the cancellation of claim 6.

Claim 34 has been amended to clarify that the expression product in the claimed pharmaceutical composition is a polypeptide.

New claims 38 and 39 claim isolated complements of the nucleic acid molecules of claims 1 and 4, respectively. Support for these claims is found in claims 1 and 4 as filed.

New claims 40 and 41 claim specific SOC3/CRAC2 nucleic acid molecules recited in the specification. Support for these claims can be found in the specification as filed, for example at page 12, lines 15-19.

No new matter has been added.

Summary of the Substance of the Interview

In the aforementioned interview of April 5, 2005, Applicant's representative discussed overcoming the utility rejection with the Examiner. In particular, Applicant's representative presented reasons supporting the existence of a specific, substantial and credible utility in the application as filed. Applicant's representative also agreed to file a declaration to support the asserted utility, in particular to support the specificity of the asserted utility in view of the

expression pattern of the claimed molecules. In addition, the remaining rejections of the Office Action were discussed, and Applicant's representative proposed amending and canceling certain claims to expedite allowance of the claims.

Rejections Under 35 U.S.C. § 101

The Examiner rejected claims 1, 4, 6-9, 12 and 34 under 35 U.S.C. § 101 as lacking utility. Applicant respectfully traverses the rejection and requests reconsideration.

Applicant asserts that the specification provides a specific, substantial and credible utility. In the previous amendment, Applicant asserted that a utility was provided at page 2, lines 23-30 of the application, wherein it was stated that the SOC3/CRAC2 sequences of the invention are useful in identifying molecules that can be used to block lymphocyte proliferation.

In discussing this asserted utility in the interview of April 5, 2005, the Examiner agreed that the asserted utility was substantial and credible, but indicated that it did not appear that the utility was specific, based on the expression pattern of SOC3/CRAC2 provided in the application. In particular, the Examiner indicated that, due to the expression pattern, one of ordinary skill in the art would not have recognized that the asserted identification of molecules that can be used to block lymphocyte proliferation would be useful.

Applicant provides herewith two declarations in support of the asserted utility. The first declaration is that of Dr. Jean-Pierre Kinet, which reviews scientific articles and a patent that were available prior to the filing of the instant application, and which also reviews data showing that the asserted methods in fact work as described. The second declaration is that of Dr. Michael Xie, which presents the data that is reviewed by Dr. Kinet.

As indicated in Dr. Kinet's declaration, the literature known at the time of filing of the instant application demonstrated that modulators of proteins that are expressed in a wide variety of tissues and cell types (including Kv1.3 and IK ion channels and calcineurin phosphatase) could be identified, and that these modulators were useful as immunosuppressants.

As described by Dr. Kinet, Kv1.3 and IK channels were known to be involved in maintaining a positive driving force for Ca^{2+} entry into lymphocytes by maintaining cell

membrane hyperpolarization. Modulators of Kv1.3 or IK activity were shown to inhibit T cell activation. Based on these precedents, one of ordinary skill in the art would reasonably expect that modulators of the SOC3/CRAC2 channel could be identified as stated in the instant application, and that these modulators would be effective in inhibiting T cell activation.

As indicated in Dr. Kinet's declaration, the data provided in Dr. Xie's declaration and attached Exhibits shows that molecules have been identified that are modulators of SOC3/CRAC2 channel activity. These molecules are effective *in vivo* in a murine mixed lymphocyte reaction (a model for transplant rejection), which is comparable to the immunosuppressive effects noted in the prior art for modulators of calcineurin, Kv1.3 channels and IK channels. Further, Dr. Kinet indicated that the data reported by Dr. Xie indicates that the molecules do not have acute toxicity when administered to animals in high doses.

Therefore, despite the wide distribution of expression of SOC3/CRAC2, the declarations provided herewith support Applicant's assertion of a specific utility in the instant application.

In view of the arguments and supporting documents provided above, Applicant respectfully requests reconsideration and withdrawal of the rejection based on 35 U.S.C. § 101.

Rejections Under 35 U.S.C. § 112

The Examiner rejected claims 1, 4, 6-9, 12 and 34 under 35 U.S.C. § 112, first paragraph, as not supported by an asserted utility or a well-established utility. Applicant respectfully requests reconsideration of the rejection based on the response to the utility rejection above.

Accordingly, withdrawal of the rejection of claims 1, 4, 6-9, 12 and 34 under 35 U.S.C. § 112 is respectfully requested.

The Examiner rejected claims 1, 6-9, 12 and 34 under 35 U.S.C. § 112, first paragraph as not supported by an adequate written description of the invention. Applicant has amended the claims and respectfully requests reconsideration of the rejection.

Applicant amended claim 1 such that it now recites nucleic acids that encode SEQ ID NO:30, the amino acid sequence of SOC3/CRAC2. Claims 6-9 have been canceled. New claims

40 and 41 recite specific nucleic acids that are described in the application (and complements thereof): nucleotides 73-3714 of SEQ ID NO:29 in claim 40 and SEQ ID NO:25 in claim 41. Each of the claimed molecules are explicitly described in the specification (nucleotides 73-3714 of SEQ ID NO:29 and SEQ ID NO:25) or are described in a way that one of ordinary skill in the art would recognize that Applicant was in possession of the molecules (complements).

Therefore the existing claims and the new claims are adequately described in the specification.

Accordingly, withdrawal of the rejection of claims 1, 6-9, 12 and 34 under 35 U.S.C. § 112 is respectfully requested.

The Examiner rejected claims 1, 4, 9, 12 and 34 under 35 U.S.C. § 112, first paragraph, as not enabled by the specification. Applicant has amended the claims and respectfully requests reconsideration of the rejection.

Claim 1 has been amended as indicated above. Claim 9 has been canceled. The other rejected claims depend from amended claim 1. Claim 1 as amended claims a nucleic acid molecule that encodes a specific amino acid sequence, SEQ ID NO:30. This sequence does not have the deficiencies alleged by the Examiner in the Office Action.

Accordingly, withdrawal of the rejection of claims 1, 4, 9, 12 and 34 under 35 U.S.C. § 112 is respectfully requested.

The Examiner rejected claim 1 under 35 U.S.C. § 112, second paragraph, as vague and indefinite for the use of the term "SOC/CRAC" and for section (b). Applicant has amended claim 1 and respectfully requests reconsideration of the rejection.

Claim 1 as amended does not contain the term "SOC/CRAC" or section (b). Accordingly, withdrawal of the rejection of claim 1 under 35 U.S.C. § 112 is respectfully requested.

The Examiner rejected claim 12 under 35 U.S.C. § 112, second paragraph, as vague and indefinite for the use of the term "unique fragment". Applicant respectfully requests reconsideration of the rejection.

Claim 12 as amended does not contain the term "unique fragment" and in fact this term was removed from the claim by a previous amendment. Accordingly, withdrawal of the rejection of claim 12 under 35 U.S.C. § 112 is respectfully requested.

The Examiner rejected claim 6 under 35 U.S.C. § 112, second paragraph for reasons of record. Applicant has canceled claim 6, rendering this rejection moot. Accordingly, withdrawal of the rejection of claim 6 under 35 U.S.C. § 112 is respectfully requested.

The Examiner rejected claim 34 under 35 U.S.C. § 112, second paragraph, as vague and indefinite for reasons of record, which pertained to the use of the term "expression product" in view of the dependence of the claim on claim 1. Applicant has amended claims 1 and 34 and respectfully requests reconsideration of the rejection.

Claim 1 as amended does not recite any nucleic acids that do not encode a protein. In fact, the nucleic acids claimed in amended claim 1 are defined as encoding a protein having the amino acid sequence of SEQ ID NO:30. Applicant also amended claim 34 to clarify that "expression product" is a polypeptide expression product of the nucleic acids recited in claim 1.

Accordingly, withdrawal of the rejection of claim 34 under 35 U.S.C. § 112 is respectfully requested.

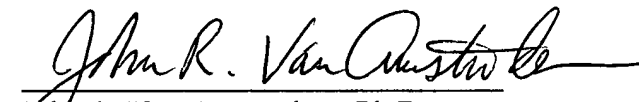
CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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